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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,425	11/15/2000	Leonard Presta	P1726R1P1	3384

7590

05/05/2003

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/05/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

713,425

Applicant(s)

PRESTA

Examiner

SAUNDERS

Group Art Unit

1644

--The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address--

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 1/23/03

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-79 is/are pending in the application.

Of the above claim(s) 1-59, 64-79 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

☒ Claim(s) 60-63 is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some* ☐ None ☐ of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ ☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Art Unit: 1644

Claims 1-79 are pending.

Applicant's election without traverse of Group IX (claims 60-63) in Paper No. 12 of 1/23/03 is acknowledged.

The following correction has been entered in the Office action mailed 10/2/02:

On form PTO-326 under "Disposition of claims" deleted "claims 1-79 is/are rejected".
Inserted "claims 1-79 are subject to restriction or election requirement."

Claims 60-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 60 must be amended to reflect the elected embodiment of Group IX. Further any residues recited in claim 60 which the disclosure has identified as being altered to reduce, rather than enhance, Fc.gamma.R binding must be deleted from claim 60.

Prior to examination over the prior art the effective filing date of claims 60-63 must be established. This date is the 11/15/00 filing date of the instant CIP application. No disclosure pertaining to the claimed subject matter was set forth in parent 08/483,588.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1644

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 60-63 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Idusogie et al. (WO 99/51642 or U.S. 6,242,195).

WO and US disclosures are equivalent. For brevity the examiner will refer only to U.S. col/line numbers.

Idusogie et al. ('195) teach existence of the IgG1 Mutant form K334A (col. 38, line 54). Instant table 9 shows this mutant from as variant no. 55 (see page 102, fifth row. Table 9 shows that this mutant has the inherent property of having increased binding to the allotypic Fc receptors Fc.gamma.RIIIA-F158 and Fc.gamma,RIIIA-V158. Thus claims 60-63 are anticipated.

While Idusogie et al. did not disclose evaluation of the binding activity of the K334A mutant to allotypic forms of Fc receptors, this mutant necessarily had the inherent property

Art Unit: 1644

shown by applicant in instant Table 9. That Idusogie et al. did not recognize this inherent property does not overcome anticipation.

Claims 60-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Idusogie et al. (6,528,624).

Idusogie et al. ('624) teach existence of mutant forms in addition to those shown by Idusogie et al. ('195). See Table 3 at col. 42.

Note mutant E333A corresponding to mutant no. 154 in instant Table 9 (page 102, third row). This table shows that this mutant has the inherent property of having increased binding to allotypic receptors Fc.gamma.RIIIIa - F158 and Fc.gamma.RIIIIa - V158. Claims 60-63 are thus anticipated.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982);

Art Unit: 1644

In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 60-63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12 and 18 of U.S. Patent No. 6,528,624. Although the conflicting claims are not identical, they are not patentably distinct from each other because as explained supra the E333A and K334A mutants shown by Idusogie et al. anticipate the rejected claims. These mutants would be encompassed by issued claims 12 and 18. Since instant and copending claims encompass common subject matter a disclaimer is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 3976. The

Art Unit: 1644

examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

April 30, 2003

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER

ART UNIT ~~182~~ 1644